

REMARKS

Claims 1-3, 9-12, 14-18, 28-35 and 38-50 are pending in the case. Claims 30 and 43 have been canceled. New claims 52-53 have been added. Claim 37 has been amended to overcome an antecedent basis problem noted by the Examiner. Claim 41 has been amended to correct a typographical error.

Claims 1-3, 9-12, 14-18, 28-35, 37, 38, 40-50 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 6,508,819 to Orbay. The applicant respectfully traverses the rejection for the following reasons.

In view of the agreement reached in the Interview of January 10, 2006, the following provides identification as to where each element of the claims is supported in the Specification. It is noted that the present Specification includes a complete copy of the Specification of U.S. Pat. No. 6,364,882 ('882 patent), which has been incorporated by reference in its entirety into the present application and from which the present application claims priority. The Specification additionally includes Figs. 29-33 and associated description from U.S. Pat. No. 6,706,046. Priority for the claimed subject matter related thereto (claim 39) goes back to at least U.S. Pat. No. 6,730,090 for reasons advanced below.

Support for the language of the claims will now be made with reference to column/line numbers of the '882 patent and figures where appropriate, unless otherwise noted.

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1. An orthopedic fixation plate, comprising:
 - a substantially rigid T-shaped plate (*col. 3, line 30*) including a head portion and a longitudinally extending shaft portion, said head portion being angled upward relative to said shaft portion (*col. 3, lines 37-39, Figs. 5 and 9*),
 - said head portion having upper and lower surfaces (*col. 3, lines 39-41*) and defining an arrangement threaded holes adapted to individually receive therein pegs having threaded heads (*col. 4, lines 1-2 and 46-47*),
 - said head portion defining a first surface area (*identified as A on Appendix Sheet 1*) on a first side of said arrangement of threaded holes of said head portion, opposite said shaft portion, and a second surface area (*identified as B on Appendix Sheet 1*) on a second side of said arrangement of threaded holes of said head portion which is on a same side as said shaft portion, said first surface area being larger than said second surface area (*See provided Appendix Sheet 2 in which the second surface area B is shown completely within the first surface area A, clearly indicating that area A is larger than area B such that original Fig. 12 from the '882 patent supports the claim*).
2. An orthopedic fixation plate according to claim 1, wherein:
 - said threaded holes define axes which are oblique relative to each other (*col. 4, lines 21-45*).
3. An orthopedic fixation plate according to claim 1, wherein:
 - said threaded holes define axes which diverge away from said lower surface of said head portion. (*col. 4, lines 21-45, col. 6, lines 10-32, and Figs. 5-6 and 16-24*)
9. An orthopedic fixation device, comprising:
 - a generally flat head portion and a longitudinally extending shaft portion angled relative to said head portion (*col. 3, lines 37-45; Fig. 11*), said head portion having upper and lower surfaces and defining a plurality of threaded holes adapted to individually receive therein pegs having threaded heads (*col. 4, lines 1-2 and 46-47*), said threaded holes defining a plurality of axes which are oblique and divergent relative to each other (*col. 4, lines 21-24; Figs. 5-6 clearly show the axes as divergent*) and at least one of which is oblique relative to said lower surface generally surrounding its corresponding threaded hole. (*See provided Figs. 17-19-MARKUP and 22-24-MARKUP on Appendix Sheet 3, which clearly visually indicate that the axes through the threaded holes are oblique relative to the lower surface generally surrounding corresponding threaded holes.*)
10. An orthopedic fixation device according to claim 9, wherein:
 - said shaft portion includes at least one hole for receiving a fastener. (*col. 5, lines 35-40, Fig. 10: 224, 226, 228, 229*)
12. An orthopedic fixation device according to claim 9, wherein:
 - all of said threaded holes are arranged along one of a line (*col. 5, line 59: "linearly arranged"*) and a smooth curve (*col. 4, line 11: "parabolic curve"*).

14. An orthopedic fixation device according to claim 9, wherein:
each of said threaded holes is oblique in two dimensions relative to the others.
(col. 4, lines 21-45, col. 6, lines 10-32, and Figs. 5-6 and 16-24)
15. An orthopedic fixation device according to claim 9, wherein:
said plurality of threaded holes consists of exactly four holes (col. 5, line 53:
"four threaded peg holes").
16. An orthopedic fixation device according to claim 9, wherein:
said shaft portion includes at least one hole for a bone fastener. (col. 3, lines 59-61)
17. An orthopedic fixation device according to claim 9, wherein:
said head portion and said shaft portion are sized and shaped for placement on the distal radius bone (col. 1, lines 60-62).
18. An orthopedic fixation device according to claim 9, wherein:
said shaft portion is relatively flat. (plate 102, Figs. 5 and 11)
28. An orthopedic fixation device, comprising:
a rigid plate portion (supported by head portion 216) and a shaft portion (supported by body portion 218), said plate portion having an upper surface and a lower surface (first and second sides 120, 122) and including four threaded holes (130, 132, 134, 136) defining four axes which diverge away from each other relative to said lower surface (Figs. 5 and 6). [This claim also fully supported by U.S. Pat. No. 6,358,250.]
29. An orthopedic fixation device according to claim 28, wherein:
said axes of said threaded holes are arranged to follow the contour of subchondral bone. (col. 5, lines 22-27; note that "subcondylar" at line 25 is a typographical error and should have been "subchondral". Correction of this error in the priority chain first appears in 6,730,090, filed May 30, 2002, at col. 4, lines 10-18.) [It is noted that the '882 patent of the §102(b) rejection also includes the erroneous term "subcondylar". However, the Examiner clearly understands the error and the intended meaning, finding that "subcondylar" in the '882 patent means "subchondral".]
31. An orthopedic fixation device according to claim 28, wherein:
said axes of said threaded holes are divergent both medial-laterally and distally.
(col. 4, lines 21-45, col. 6, lines 10-32, and Figs. 5-6 and 16-24)
32. An orthopedic fixation device according to claim 28, wherein:
said plate portion and said shaft portion are sized and shaped for placement at the distal radius bone. (col. 1, lines 60-62, col. 5, lines 7-9)
33. An orthopedic fixation device according to claim 28, wherein:
said shaft portion includes at least one hole for receiving a bone fastener. (col. 3, lines 59-61)

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34. An orthopedic fixation device according to claim 28, wherein:
said shaft portion is relatively flat. (*plate 102, Figs. 5 and 11*)
35. An orthopedic fixation device according to claim 34, wherein:
said shaft portion is angled relative to said plate portion. (*col. 3, lines 37-39*)
37. An orthopedic fixation system, comprising:
a) a rigid device having an upper surface and a lower surface, said device having a head portion and a shaft portion ('882 patent: *col. 3, lines 30, 37-41; U.S. Pat. No. 6,730,090: rigid plate portion 14 and nail section 22, with plate portion having lower and upper surfaces 32, 33*); and
b) a plurality of elements for supporting the bone extending from said lower surface of said head portion ('882 patent: *col. 4, lines 52-54, col. 5, lines 23-26; '090 patent: col. 3, lines 19-29*), said elements being obliquely angled relative to each other and none of said elements converging in angle toward another element. ('882 patent: *col. 4, lines 21-45, col. 6, lines 10-32, and Figs. 5-6 and 16-24. This is clearly supported by pegs being threadably engaged within the threaded peg holes and extending in alignment with the respective axes of the peg holes, with the axes all diverging from each other as shown. Moreover, Fig. 9 shows pegs 108 diverging from each other. Also '090 patent: col. 3, lines 23-29: pegs in "fanned arrangement" and Figs. 6-7.*)
38. An orthopedic fixation system according to claim 37, wherein:
said plurality of elements includes at least three elements attached to said head portion of said device in a substantially linear arrangement. ('882 patent: *col. 5, lines 53-59; '090 patent: col. 3, lines 19-23, Figs. 6 and 7*)
39. An orthopedic fixation system according to claim 38, wherein:
said linear arrangement is generally parallel to said shaft portion. ('090 patent: *col. 3, lines 19-21: pegs longitudinally displaced along narrow head and Figs. 6-7*)
40. An orthopedic fixation system according to claim 38, wherein:
said linear arrangement is generally medial-lateral across said head portion. (*col. 5, lines 60-62*)
41. An orthopedic fixation system according to claim 37, wherein:
said plurality of elements includes at least three elements attached to said head portion of said plate in a curvilinear arrangement. (*col. 4, lines 1-2 and 10-11*)
42. An orthopedic fixation system according to claim 37, wherein:
said axes of said elements are arranged to follow the contour of subchondral bone. (*col. 5, lines 22-27: note that "subcondylar" at line 25 is a typographical error and should have been "subchondral". Correction of this error in the priority chain first appears in 6,730,090, filed May 30, 2002, at col. 4, lines 10-18.*) [It is noted that the '882 patent of the §102(b) rejection also includes the erroneous term "subcondylar".]

However, the Examiner clearly understands the error and the intended meaning, finding that "subcondylar" in the '882 patent means "subchondral".

44. An orthopedic fixation system according to claim 37, wherein:
said axes of said elements are divergent both medial-laterally and distally. (*col. 4, lines 21-45, col. 6, lines 10-32, and Figs. 5-6 and 16-24*)
45. An orthopedic fixation system according to claim 37, wherein:
said head portion and said shaft portion are sized and shaped for placement on the distal radius bone. (*col. 1, lines 60-62, col. 5, lines 7-9*)
46. An orthopedic fixation system according to claim 37, wherein:
said head portion is angled upwards relative to said shaft portion. (*col. 3, lines 37-39, Figs. 5 and 9*)
47. An orthopedic fixation system according to claim 37, wherein:
said head portion and said shaft portion are in a T-shaped configuration. (*col. 3, line 30, Figs. 1, 10, 12, et al.*)
48. An orthopedic fixation system according to claim 37, wherein:
said shaft portion includes at least one hole for receiving a bone fastener. (*col. 3, lines 59-61*)
49. An orthopedic fixation system according to claim 37, wherein:
at least one of said elements is a peg which includes a threaded head which is coupled within a threaded hole in said head portion of said plate. (*col. 4, lines 46-50*)
50. An orthopedic fixation system according to claim 49, wherein:
said peg includes a threaded shaft portion. (*col. 4, lines 46-50*)
52. An orthopedic fixation system according to claim 37, wherein:
said elements are directly connected to said head portion. (*col. 4, lines 46-54: the threaded coupling between the pegs and threaded holes in the head portion is a direct coupling.*)
53. An orthopedic fixation system according to claim 37, wherein:
said elements are threadably attached to said head portion. (*col. 4, lines 46-54: the threaded coupling between the pegs and threaded holes in the head portion.*)

In view of the foregoing, claims 1-3, 9-10, 12, 14-18, 28-29, 31-35, 37-38, 40-42, 44-50 and 52-53 are entitled to an effective filing date at least as early as the filing date of the '882 patent, March 13, 2000. In addition, claim 39 is entitled to an effective filing

date at least as early as the filing date of the '090 patent, May 30, 2002. The Specification has been amended as necessary to include explicit description of that which is clearly shown in the figures and claimed. No new matter is added.

With the effective filing date of March 13, 2000, the rejection of claims 1-3, 9-10, 12, 14-18, 28-29, 31-35, 37-38, 40-42 and 44-50 as anticipated by the '819 patent to Orbay is respectfully traversed. With respect to claim 39, the '819 patent fails to teach or suggest a substantially linear arrangement of at least three elements attached to the head portion, wherein the linear arrangement is *generally parallel to said shaft portion*.

Claims 37-39, 44 and 46-48 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,190,544 to Chapman. The applicant traverses the rejection for the following reasons.

A rejection based on anticipation "requires that all of the elements and limitations of the claim [be] found within a single prior art reference." *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 U.S.P.Q. 1001, 1010 (Fed. Cir. 1986)(citing *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138, 231 U.S.P.Q. 644, 646 (Fed. Cir. 1986)). "If it is necessary to reach beyond the boundaries of a single reference to provide missing disclosure of the claimed invention, the proper ground [for rejection] is not a §102 anticipation." *Id.* Chapman does not show all the elements of claim 37. The language of claim 37 requires a plurality of elements for supporting bone *extending from the head portion* of the device. It also requires that the elements be obliquely angled

relative to each other with *none of the elements converging in angle toward another element*.

In the device shown in Fig. 6 of Chapman there is only a single element extending through one hole 53 of the head portion (no plurality of elements): epiphyseal/metaphyseal implant 1 (See Appendix Sheet 4). The "head portion" is commonly understood by those skilled in the art to refer to the portion of a device which is located at the metaphysis or enlarged end portion of a long bone, whereas the shaft of a device is commonly understood to be that portion which is located over the diaphysis of a long bone. None of screws 89 through screw holes 55, 57, 59 located in elongate plate portion 45 (a shaft portion) are in the head portion of the plate. Given that there is only a single element extending from the head portion, the Chapman system cannot anticipate the requirement of non-convergence of the elements; such only has relevance where the system includes multiple elements in the head portion.

In the device of Fig. 29, the requirements of multiple elements is met, but the requirement that none of the elements converge toward another is not met. Fig. 31 (the same embodiment as Fig. 29) clearly shows screw **convergence** (see Appendix Sheet 5). The fact that a prior art device may be modified to meet the claimed limitations does not satisfying the requirements of an anticipation rejection. In order to maintain an anticipation rejection "the identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

With respect to claim 38, Fig. 6 has a head portion with a single element coupled thereto. Fig. 29 has a head portion with multiple screws inserted therein, but not in linear arrangement. With respect to claim 39, the linear arrangement of screws in claim 6 is along a shaft portion, not a head portion. With respect to claim 44, the screws shown in Chapman are not all divergent.

Claims 37, 38, 40, 46 and 48 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 4,565,193 to Streli. The applicant respectfully traverses the rejection for the following reason. The claims require that the elements be *obliquely angled relative to each other*. The Examiner states that in view of defined angle beta this limitation is satisfied. However, angle beta is the same for each prong 5, such that the prongs lie in a common plane 30. (Col. 3, lines 36-38) The prongs are also substantially parallel to each other. Thus, the prongs are not obliquely angled **relative to each other**.

Claims 37, 41, 44, 46 and 48 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,749,872 to Kyle. The applicant respectfully traverses the rejection for the following reasons. Claim 37 requires the elements "being obliquely angled relative to each other and none of said elements *converging in angle toward* another element." However, as clearly seen from Fig. 1, lag screws 38 in Kyle do converge in angle toward another. As seen from marked-up Fig. 1 of Kyle (Appendix Sheet 6), the ends of the identified screws are clearly closer than their heads and converge toward a common point. Therefore, Kyle does not anticipate the claimed invention.

Claims 52 and 53 have been added to more completely claim the invention. Such claims require a direct connection between the elements and the head portion of the plate (i.e., such that the elements can be immobilized relative to the plate even without the presence of bone) and the particular coupling of threads between the elements and the head portion. In all embodiments of Chapman and Kyle, the screws are not directly coupled to the plate at the screw holes and a threaded coupling is not used. In both Chapman and Kyle, the screws are directly connected to the bone with the plate simply an intervening structure. Removing the bone from the system would cause the screws to lose any coupling to the plate. There is no teaching or suggestion in Chapman or Kyle for directly connecting the screws 38 to the plate. Therefore, claims 52 and 53 are allowable over the cited art.

Claims 9-12, 14, 16, 18, 28, 29, 31, 33-35 stand rejected as obvious over U.S. Pat. No. 5,749,872 to Kyle in view of U.S. Pub. No. 2002/0156474 to Wack (filing date April 20, 2001) and U.S. Pub. No. 2001/0021851 to Eberlein (filing date January 18, 2001) is also overcome. For the reasons identified above, the effective filing date for these claims is at least as early as March 13, 2000. Therefore, the rejection is traversed.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain

outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,



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APPENDIX

Sheet 1: Fig. 12MARKUP1 (6,364,882 to Orbay)

Sheet 2: Fig. 12MARKUP2 ('882)

Sheet 3: Figs. 17 – 24MARKUP ('882)

Sheet 4: Marked-up Figs. 7 and 16 (U.S. Pat. No. 5,190,544 to Chapman)

Sheet 5: Marked-up Fig. 31 (U.S. Pat. No. 5,190,544 to Chapman)

Sheet 6: Marked-up Fig. 1 (U.S. Pat. No. 5,749,872 to Kyle)